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March 12, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Re:

U.S. Patent Application No.: 09/955485

For: INCREASING CEREBRAL BIOAVAILABILITY OF DRUGS

Inventors: Moskowitz, Michael A. et al.

Filed: September 19, 2001 Our Ref. No.: ENI-005

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

- 1. Supplemental Information Disclosure Statement;
- 2. A copy of the Supplementary Partial European Search Report;
- 3. A copy of U.S. Patent Application No. 09/273445;
- 4. A copy of U.S. Patent Application No. 10/688721;
- 5. **PTO Form SB/08**;
- 6. Copies of references cited in PTO Form SB/08 (11); and
- 7. A Return Postcard.

Please charge the necessary fees in the amount of \$180.00 due in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on:

March 12, 2004

Date

Danielle L. Herritt, Registration No. 43,670

Respectfully submitted,
LAHIVE & COCKFIELD, LLP

Danielle L. Herritt

Registration No. 43,670

Attorney for Applicants



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Moskowitz, Michael A. et al.

Group Art Unit: 6114

Serial No.: 09/955485

Examiner: Spivack, Phyllis G.

Filed: September 19, 2001

For: INCREASING CEREBRAL BIOAVAILABILITY

OF DRUGS

Attorney Docket No.: ENI-005

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Certificate of First Class Mailing (37 CFR §1.8(a))

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March 12, 2004

By:

Date of Signature and of Mail Deposit

Danielle L. Herritt Reg. No. 43,670

Attorney for Applicants

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants and their Attorney are aware of the following additional publications, listed on the attached PTO Form SB/08, and in accordance with 37 CFR §1.97 hereby submit these publications for the Examiner's consideration. A copy of each cited publication is enclosed. References D1, D3-5, and D9-D11 were cited in a Supplementary Partial European Search Report dated May 13, 2003 during the prosecution of EP 00 91 9452.3 which corresponds to the above referenced application. A copy of this report is also enclosed.

Serial Number: 09/955485 Page -2- Group Art Unit: 1614

In addition, Applicants direct the Examiner's attention to the following United States patent applications, copies of which are enclosed.

U.S. Ser. No.	Filing Date	
09/273445	03-19-1999	
10/688721	10-15-2003	

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, the Applicants understand that the Examiner will make an independent evaluation of the cited publications.

In accordance with 37 CFR §1.97(c)(2) and §1.17(p), please charge the \$180.00 submission fee to our Deposit Order Account No. 12-0080. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 12-0080.

Respectfully submitted, LAHIVE & COCKFIELD, LLP

Danielle L. Herritt Registration No. 43,670

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28 State Street Boston, MA 02109 (617) 227-7400

Date: March 12, 2004

GAD/DFS/DLH/krj

Enclosures

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/B/PTO 09/955485 Application Number INFORMATION DISCLOSURE September 19, 2001 Filing Date STATEMENT BY APPLICANT Moskowitz, Michael A. et al. First Named Inventor 1614 Art Unit (Use as many sheets as necessary) Spivack, Phyllis G. Examiner Name ENI-005 1 1 of Sheet Attorney Docket Number

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	D1	5,648,101	07-15-1997	Tawashi	
	D2	US 2003/0114515 A1	06-19-2003	Kaesemeyer	

FOREIGN PATENT DOCUMENTS						
	Cite	Foreign Patent Document	Publication Date MM-DD-YYYY	te Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				T ⁶
	D3	WO 00/20382 A1	04-13-2000	SRI INTERNATIONAL		
	D4	WO 00/23102 A1	04-27-2000	NEW YORK UNIVERSITY		
	D5	WO 00/29033 A2,A3	05-25-2000	THE GENERAL HOSPITAL CORPORATION		
	D6	WO 00/62614 A1	10-26-2000	NITROSYSTEMS, INC.		
	D7	WO 01/28499 A2,A3	04-26-2001	NITROSYSTEMS, INC.		
	D8	WO 02/00212 A1	01-03-2002	KAESEMYER, Wayne H.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	, , , , , , , , , , , , , , , , , , ,			
	D9	Mayhan, W.G. "Role of nitric oxide in histamine-induced increases in permeability of the blood-brain barrier." <i>Brain Research</i> 743:70-76 (1996).			
	D10	Minami, T. et al. "Roles of nitric oxide and the prostaglandins in the increased permeability of the blood-brain barrier caused by lipopolysaccharide." 5:35-41 (1998).			
	D11	Morikawa, E. et al. "L-arginine dilates rat pial arterioles by nitric oxide-dependent mechanisms and increases blood flow during focal cerebral ischaemia." Br. J. Pharmacol. 107:905-907 (1992).			

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date	
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^{&#}x27;Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.